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OKAMURA6

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EXAMINER

BHAT, NARAYAN KAMESHWAR

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/521,176	Applicant(s) OKAMURA ET AL.	
	Examiner NARAYAN K. BHAT	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-22, 31 and 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-22 and 31-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

FINAL ACTION

1. This office action is written in reply to applicant's correspondence filed September 8, 2008. Claim 17 was amended. Claims 23-30 were cancelled. New claims 31-32 were added. Applicant's amendments requiring a nucleic acid molecule bonded covalently to the chemically modifying layer necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**.
2. Claims 17-22 and 31-32 are pending in this application and are under prosecution.

Amendments to Claims

3. Amendments to the claim 17 have been reviewed and entered.

New Claims

4. New claims 31 and 32 have been reviewed and entered.

Notes for the Applicant

5. Applicant cannot rely upon the foreign priority papers to overcome the above rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15. Applicant has not provided the English translation of the certified copy of the original document filed with the application. If Applicant files the requested documents meeting the requirement as cited in 37 CFR 1.55, the 102(a) rejection set forth in this office action may be withdrawn.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 17-20 and 31 are rejected under 35 U.S.C. 102(a) as being anticipated by Consolandi et al (Nucleotides, Nucleotides and Nucleic Acids, 2002, 21, 561-580).

Claim 17 recites following structural components: a) a substrate, b) positively charged electrostatic layer on the substrate, c) a chemically modifying layer on the electrostatic layer, d) a nucleic acid molecule covalently bonded to the chemically modifying layer. Consolandi et al teaches structural components 'a' to 'd'

Regarding structural component 'a' Consolandi et al teaches a substrate (Fig. 1a top left panel, # 1).

Regarding structural component 'b' Consolandi et al teaches an electrostatic layer, i.e., poly-L-lysine layer comprising a positively charged amino group compound on the substrate (Fig. 1a, # 2, pg. 567, paragraph 4, and line 3).

Regarding structural component 'c' Consolandi et al teaches a chemically modifying layer, i.e., PDITC layer on the electrostatic layer (Fig. 1a, # 3, pg. 567, paragraph 4, lines 4-5) making it possible to introduce a isothiocyanate function group capable of covalently binding to a nucleic acid molecule (Fig. 1a, second panel from the bottom, pg. 567, paragraph 4, line 7).

Regarding structural component 'd', Consolandi et al teaches a nucleic acid molecule bonded to the chemically modifying layer (Fig. 1a, # 4, Bottom panel).

Regarding claim 18, Consolandi et al teaches that chemically modifying layer comprising poly (acrylamide-co-acrylic acid) layer and contains a carboxyl group (Fig. 1b. third panel from the top, pg. 567, paragraph 4).

Regarding claim 19, Consolandi et al teaches that electrostatic layer comprising poly L-lysine has non-covalent amino group distal to the substrate (Fig. 1a, # 2). Therefore, electrostatic layer include an amino group containing compound that does not covalently bound to the substrate.

Regarding claim 20, Consolandi et al teaches a solid support wherein an electrostatic layer comprises an amino group-containing polymer, polylysine (Fig. 1a, # 2) and further teaches that the polymer binds covalently to the substrate via APTES and also has free amino group to introduce functional group (Fig. 1a, # 3), thus teaching a compound containing an amino group at the terminus to which the substrate does not bind.

Regarding claim 31, Consolandi et al teaches that nucleic acid molecule is immobilized as a spot (Fig. 3a).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 17-20, 22 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mao et al (WO 03/020425 filed Aug. 28, 2002) in view of Mirus et al (WO 01/02538 published Jan. 11, 2001).

Claim 17 recites following structural components: a) a substrate, b) positively charged electrostatic layer on the substrate, c) a chemically modifying layer on the electrostatic layer, d) a nucleic acid molecule covalently bonded to the chemically modifying layer. Mao et al teaches structural components 'a' to 'd' except for explicitly teaching covalent linking of nucleic acids.

Regarding structural component 'a' Mao et al teaches a substrate (Fig. 1F and pg. 9, line 3).

Regarding structural component 'b' Mao et al teaches an electrostatic layer, i.e., first layer comprising a positively charged amino group compound on the substrate (Fig. 1F, # first layer, pg. 9, lines 1-2, pg. 14, and lines 11-15).

Regarding structural component 'c' Mao et al teaches a chemically modifying layer, i.e., a second layer on the electrostatic layer (Fig. 1F, # second layer, pg. 9, lines 7-10). Mao et al further teaches that second layer comprises polyacrylic acid (pg. 14, lines 11-19) containing carboxyl functional groups (pg. 22, lines 21-22) capable of covalently binding to a nucleic acid molecule (pg. 8, lines 19-27). While, Mao et al suggests bound nucleic acid, the reference does not specifically teach a nucleic acid molecule bonded covalently to the chemically modifying layer.

Regarding claim 18, Mao et al teaches the second layer, i.e., chemically modifying layer contains a carboxyl group (pg. 22, lines 21-22).

Regarding claim 19, Mao et al teaches a solid support wherein the first layer, i.e., an electrostatic layer comprises an amino group-containing polymer, polylysine (pg. 14, lines 11-15) and further teaches that the polymer binds to the substrate by an electrostatic interactions (pg. 4, lines 15-16), thus teaching an amino group containing compound that does not covalently bind to the substrate.

Regarding claim 20, Mao et al teaches that the first layer, i.e., an electrostatic layer comprises an amino group-containing compound (pg. 14, lines 11-15) and further teaches that the polymer binds to the substrate through covalent bonds (pg. 4, lines 15-16). Mao et al also teaches that the first layer comprising of amino group forms an amide bond with the carboxyl group of the polymer of the second layer (pg. 20, lines 25-29) thus teaching a compound containing an amino group at the terminus to which the substrate does not bind.

Regarding claim 22, Mao et al teaches a solid support comprising gold metal (pg. 9, lines 27-28), which is a highly thermal conducting metal and has a thermal conductivity of 318 W/m.K, i.e., 3.18 W/cm.K as further evidenced by Langer et al (Fig. 5, See legend, pg. 1512, column 1, paragraph 1). It is noted that the reference of Langer et al is used to confirm the known property of gold metal.

Regarding claim 31, Mao et al clearly suggest nucleic acid molecules are immobilized on the solid support (pg. 8, lines 24-28) but are silent about immobilizing as a spot.

Regarding claim 17, Mao et al suggests bound nucleic acid, however, the reference does not specifically teach a nucleic acid molecule bonded covalently to the chemically modifying layer.

However, a nucleic acid molecule bonded covalently to the chemically modifying layer and immobilizing nucleic acid as a spot were known in the art at the time of the claimed invention was made as taught by Mirus et al.

Mirus et al teaches a solid support for nucleic acid immobilization comprising a substrate (pg. 4, line 30) and further teaches a chemically modifying layer, polyanion layer making it possible to introduce a carboxyl functional group (pg. 5, lines 3-9). Mirus et al further teaches a nucleic acid molecule bonded covalently to the chemically modifying layer (pg. 3, lines 7-10).

Mirus et al also teaches that the nucleic acid molecule is immobilized as a spot (pg. 10, lines 3 and 29-30).

Mao et al suggests the covalent binding of nucleic acids to the functional groups on the surface of the chemically modified layer comprising poly acrylic acids (pg. 8, lines 23-27). Mirus et al teaches the covalent bonding of nucleic acids to the carboxyl groups on the chemically modified layer and immobilizing nucleic acids as a spot on the substrate, thus meeting the limitation of structural components recited in claims 17 and 31.

Mirus et al also teaches that covalent binding of nucleic acids increases the concentration of the nucleic acids irrespective of their size on the support, forming a three dimensional lattice and increases the sensitivity of target detection (Tables 1-4, pg. 15, lines 9-13).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the nucleic acid immobilization to the substrate of Mao et al with covalent attachment of nucleic acid with carboxyl functional group on the substrate of Mirus et al with a reasonable expectation of success with the expected benefit of covalent binding of nucleic acids increasing the concentration of the nucleic acids irrespective of their size on the support, forming a three dimensional lattice and increasing the sensitivity of target detection as taught by Mirus et al (Tables 1-4, pg. 15, lines 9-13).

11. Claims 17, 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mao et al (WO 03/020425 filed Aug. 28, 2002) in view of Mirus et al (WO 01/02538

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published Jan. 11, 2001) as applied to claims 17 and 19 as above and further in view of Woo et al (USPN 5,929,194 issued July 27, 1999).

Teachings of Mao et al and Mirus et al regarding claims 17 and 19 are described in this office action in section 10.

Regarding claim 21, Mao et al teaches a variety of amino group containing compounds including polylysine (pg. 5, line 1-8). Mao et al and Mirus et al are silent about that amino group containing compound polyarylamine. However, amino group containing compound polyarylamine was known in the art before the claimed invention was made as taught by Woo et al, who teaches polyarylamine for coating substrates and forming films on the substrate carrying positive charges (column 4, lines 8-10). Woo et al further teaches that coatings with polyarylamine makes the support solvent resistant and are useful as a fluorescent coatings, as a protective coatings for electronic devices (column 4, lines 10-11, column 14, lines 13-17).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the substrate of Mao et al and Mirus et al with the polyarylamine coated substrate of Woo et al with a reasonable expectation of success with the expected benefit of generating fluorescent coatings, protective coatings for electronic devices as taught by Woo et al (column 14, lines 13-17).

12. Claims 17 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mao et al (WO 03/020425 filed Aug. 28, 2002) in view of Mirus et al (WO 01/02538

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published Jan. 11, 2001) as applied to claim 17 as above and further in view of Bertrand et al (Macromol. Rapid Commun., 2000, 21, 319-348).

Teachings of Mao et al and Mirus et al regarding claim 17 are described in this office action in section 7.

Regarding claim 32, Mao et al teaches that that electrostatic layer comprises of varying thickness (pg. 21, lines 27-28). Mao et al and Mirus et al are silent about the thickness of the electrostatic layer is 1 to 500 micron. However, the thickness of the electrostatic layer was known in the art at the time of the claimed invention was made as taught by Bertrand et al.

Bertrand et al teaches a solid support comprising a electrostatic layer, wherein the thickness of the of the layer is from few angstroms to micrometer (Fig. 1 and pg. 319, column 2, lines 4-5) and further teaches that electrostatic layer is very stable against mechanical stress or solvents (pg. 325, column 1, lines 1-3).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the substrate of Mao et and Mirus et al with the electrostatic layer of micrometer thickness of Bertrand et al with a reasonable expectation of success with the expected benefit of having electrostatic layer, which is very stable against mechanical stress or solvents (pg. 325, column 1, lines 1-3).

Response to remarks from the Applicants

Claim rejections under 35 U.S.C. § 102(a) and 102(e)

13. Applicant's arguments with respect to claim 17 as anticipated by Mao et al have been fully considered but are moot in view of withdrawal of the previous rejection and new grounds of rejection set forth in this office action as necessitated by claim amendments (Remarks, pg. 5, paragraphs 1-3).

Applicant's arguments with respect to claim 22 as anticipated by Mao et al and further evidenced by Langer et al have been fully considered but are moot in view of withdrawal of the previous rejection and new grounds of rejection set forth in this office action as necessitated by claim amendments (Remarks, pg. 5, paragraphs 4-5).

Applicant's reiterates that Mao et al do not disclose nucleic acids on the substrate.

Teachings of Mao et al as it pertains to the rejection set forth in this office action are addressed under 103(a) rejection.

Claim rejections under 35 U.S.C. § 103(a)

14. Applicants argue that "Mao et al do not disclose nucleic acid molecule immobilized on the substrate" and this argument is not persuasive because as described in this office action in section 10, Mao et al suggests the covalent binding of nucleic acids to the substrate. Mirus et al teaches the covalent bonding of nucleic acids to the carboxyl groups on the chemically modified layer and immobilizing nucleic acids.

Applicants argument with respect to claim 31 have been fully considered but are not persuasive, because newly added claim has been rejected in this office action over Mao et al and Mirus et al (section 10).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., primers immobilized in different regions) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Since Mirus et al teaches the nucleic acid immobilization as a spot, Applicants arguments are not persuasive (Remarks, pg. 5, paragraph 2).

With regard to claim 21, Applicants further reiterating that Mao et al do not disclose nucleic acids at the surface of the solid support and the argument is not persuasive for the reasons as described above.

In response to applicant's arguments regarding claim 21 against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, claim 21 is rejected in this office action over Mao et al, Mirus et al and Woo et al. As described in this office action, the electrostatic layer is taught by Mao et al. Mao et al also teaches electrostatic layer is made of a variety of amino group containing compounds (pg. 5, lines 1-8) and Woo et al

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teaches polyarylamine compound and further teaches that compound capable of forming films carrying charges (i.e., electrostatic layer) and layer is further cross-linkable and extendable (Abstract). Since Mao et al, Mirus et al and Woo et al teaches the structural components recited in claim 21, Applicants arguments are not persuasive.

Conclusion

15. No claims are allowed.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Narayan K. Bhat whose telephone number is (571)-272-5540. The examiner can normally be reached on 8.30 am to 5 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla can be reached on (571)-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Narayan K. Bhat/

Examiner, Art Unit 1634

/BJ Forman/

Primary Examiner, Art Unit 1634